Application No. 10/568,329

May 13, 2009

Response to Office Action Dated March 13, 2009

AMENDMENTS TO THE CLAIMS:

Claim 1 (Previously Presented). A process for the preparation of a recombinant polypeptide, comprising the steps of

- a) fermenting a prokaryotic host cell in a fermentation medium, the host cell comprising a periplasm and being transformed with a recombinant expression system capable of effecting secretion of the polypeptide into the periplasm, wherein the fermentation is performed in the fermentation medium under conditions such that the polypeptide is secreted into the periplasm of the host cell,
- b) interrupting the further processing of the host cell in the fermentation medium and maintaining the host cell in the medium under defined conditions of temperature and pH prior to extraction of the polypeptide, and
- c) concentrating the fermentation medium by centrifugation or micro filtration prior to interruption of further processing is interrupted in step b).

Claim 2 (Cancelled).

Claim 3 (Previously Presented). A process according to claim 1, wherein the further processing of the host cell in the fermentation medium is interrupted for from about one hour to about 72 hours.

Claim 4 (Previously Presented). A process according to claim 1, wherein the further processing of the host cell in the fermentation medium is interrupted for from about 12 hours to about 48 hours.

Claim 5 (Previously Presented). A process according to claim 1, wherein the further processing of the host cell in the fermentation medium is interrupted for from about 12 hours to about 24 hours.

Claim 6 (Previously Presented). A process according to claim 1, wherein the interruption of the further processing of the host cell in the fermentation medium is performed at a temperature of from about 2°C to about 65°C.

Claim 7 (Previously Presented). A process according to claim 1, wherein the interruption of the further processing of the host cell in the fermentation medium is performed at a temperature of from about 4°C to about 25°C. Application No. 10/568,329 May 13, 2009

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Claim 8 (Previously Presented). A process according to claim 1, wherein the interruption of the further processing of the host cell in the fermentation medium is performed at a temperature of from about 10°C to about 25°C.

Claim 9 (Previously Presented). A process according to claim 1, wherein the pH of the fermentation medium is maintained at a pH of from about 4 to about 10 during step b).

Claim 10 (Previously Presented). A process according to claim 1, wherein the pH of the fermentation medium is maintained at a pH of from about 5 to about 9 during step b).

Claim 11 (Previously Presented). A process according to claim 1, wherein the pH of the fermentation medium is maintained at a pH of from about 6 to about 8 during step b).

Claim 12 (Previously Presented). A process according to claim 1, wherein the pH of the fermentation medium is maintained at about 7 during step b).

Claim 13 (Previously Presented). A process according to claim 1, wherein the further processing of the host cell in the fermentation medium is interrupted for from about 12 to about 48 hours and at a temperature of from about 4°C to about 25°C.

Claim 14 (Previously Presented). A process according to claim 1, wherein the fermentation medium is concentrated prior to step b).

Claim 15 (Cancelled).

Claim 16 (Previously Presented). A process according to claim 1, wherein step b) is performed in a fermenter.

Claim 17 (Previously Presented). A process according to claim 1, wherein the prokaryotic host cell comprises a Gram-negative bacterium.

Claim 18 (Original). A process according to claim 17, wherein the Gram-negative bacterium is selected from the group consisting of Escherichia sp., Pseudomonas sp., Enterobacter sp., Erwinia sp., Campylobacter sp., Proteus sp., Aeromonas sp. and Vitreoscilla sp.

Claim 19 (Previously Presented). A process according to claim 17, wherein the Gramnegative bacterium comprises *Escherichia coli*.

Claim 20 (Previously Presented). A process according to claim 1, wherein the recombinant polypeptide is selected from the group consisting of an antibody, a hormone, and an immunomodulating agent.

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Claim 21 (Previously Presented). A process according to claim 1, wherein the recombinant polypeptide is selected from the group consisting of a growth hormone, a growth factor, an interferon, a cytokine, an enzyme, an enzyme inhibitor, and an antibody fragment.

Claim 22 (Previously Presented). A process according to claim 1, wherein the recombinant polypeptide is selected from the group consisting of a Fab-fragment, human growth hormone, interferon alpha-2b, and granulocyte colony-stimulating factor.

Claim 23 (Cancelled).

Claim 24 (Previously Presented). A process for the preparation of a recombinant polypeptide, comprising the steps of

- a) fermenting a prokaryotic host cell in a fermentation medium, the host cell comprising a periplasm and being transformed with a recombinant expression system capable of effecting secretion of the polypeptide into the periplasm, wherein the fermentation is performed in the fermentation medium under conditions such that the polypeptide is secreted into the periplasm of the host cell,
- b) interrupting the further processing of the host cell in the fermentation medium and maintaining the host cell in the medium under defined conditions of temperature and pH prior to extraction of the polypeptide, and

 c) concentrating the fermentation medium by centrifugation or micro filtration prior to or after further processing is interrupted in step b).

Claim 25 (Previously Presented). A process according to claim 24, wherein the further processing of the host cell in the fermentation medium is interrupted for from about one hour to about 72 hours.

Claim 26 (Previously Presented). A process according to claim 24, wherein the further processing of the host cell in the fermentation medium is interrupted for from about 12 hours to about 24 hours.

Claim 27 (Previously Presented). A process according to claim 24, wherein the interruption of the further processing of the host cell in the fermentation medium is performed at a temperature of from about 2°C to about 65°C.

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Claim 28 (Previously Presented). A process according to claim 24, wherein the interruption of the further processing of the host cell in the fermentation medium is performed at a temperature of from about 10°C to about 25°C.

Claim 29 (Previously Presented). A process according to claim 24, wherein the pH of the fermentation medium is maintained at a pH of from about 4 to about 10 during step b).